

## **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listing, of claims in the application:

### **LISTING OF CLAIMS**

1. (Currently amended) A sprayable composition for topical application, comprising:
    - from about 0.0001% to about 30% of at least one medicament for systemic or topical availability,
    - at least one film former, ~~and~~
    - at least one vehicle; and at least one component selected from the group
      - at least one permeation enhancer;
      - at least one solubilizer;
      - at least one plasticizer; and
      - at least one water soluble additive  - the composition forming a stable, breathable film upon application to a surface.
2. The composition according to claim 1, comprising from about 0.0001% to about 10% of the at least one medicament.
  3. The composition according to claim 1, comprising from about 0.0001% to about 5% of the at least one medicament.
  4. The composition according to claim 1, wherein the film former comprises from about 0.0001% to about 10% of the composition.

5. (Canceled)
6. (Currently Amended) The composition according to claim ~~5~~1, comprising wherein the at least one permeation enhancer in an amount of ~~comprises~~ from about 0.0001% to about 8% of the composition.
7. (Canceled)
8. (Currently Amended) The composition according to claim ~~7~~ 1, comprising wherein the at least one solubilizer in an amount of ~~comprises~~ from about 0.0001% to about 10% of the composition.
9. (Canceled)
10. (Currently Amended) The composition according to claim ~~9~~ 1, comprising wherein the at least one plasticizer in an amount of ~~comprises~~ from about 0.0001% to about 10% of the composition.
11. (Currently Amended) The composition according to claim 1, the composition further comprising at least one water soluble additive in an amount of from about 0.0001% to about 7% ~~of at least one water soluble additive~~.
12. The composition according to claim 1, wherein the at least one medicament is locally or transdermally available.
13. (Canceled)

14. The composition according to claim 1, wherein the composition comprises at least one medicament which is released from the composition immediately upon application to a biological surface.

15. The composition according to claim 1, wherein the composition comprises at least one medicament which is released from the composition over an extended period of time after application to a biological surface.

16. (Canceled)

17. The composition according to claim 1, wherein the at least one medicament is selected from the group consisting of anti-emetics, anti-anginals, anti-inflammatory agents, steroids, steroid hormones, bronchodilators, drugs used to treat osteoporosis, drugs used to treat incontinence, antidepressants/anxiolytics, antimigraine agents, agents used in smoking cessation therapy, antidiarrheals, antiulcerants, anticholinergics, anticonvulsants, drugs for mood disorders/obsessive compulsive disorder, ACE inhibitors, calcium channel blockers, antihypertensives/diuretics, antiobesity drugs, hormonal peptides and analogues, drugs for benign prostatic hyperplasia/urinary retention and erectile dysfunctions, antiparkinson agents such as dopamine agonists and MAO inhibitors, drugs for sleep disorders and antidiabetic agents.

18. The composition according to claim 1, wherein the at least one medicament is selected from the group consisting of scopolamine, nitroglycerine, clonidine isosorbide dinitrate, propranolol hydrochloride, timolol maleate, clonazepam, verapamil, diclofenac sodium, naproxen sodium, ibuprofen, ketoprofen, indomethacin, piroxicam, ketorolac, tromethamine, nimesulide, hydrocortisone and esters thereof, dexamethasone, fluocinolone acetonide and betamethasone

and salts thereof, estradiol and norethisterone or their pharmaceutically acceptable salts and combinations thereof, testosterone, progesterone, salbutamol and salts thereof, bambuterol, salmeterol xinafoate, fluticasone propionate, mometasone furoate, budesonide, beclomethasone dipropionate, sodium cromoglycate or isoprenaline sulphate, alendronic acid, pamidronic acid, etidronic acid or salts thereof, vasopressin, oxybutynin, imipramine, mitrazapine, desipramine, naratriptan, zolmitriptan, sumatriptan, nicotine, loperamide, misoprostol, hyoscyamine, atropine, trihexyphenidyl, lorazepam, diazepam, tiagabine, fluoxetine, paroxetine, lisinopril,trandolapril, captopril, amlodipine, felodipine, prazosin, amiloride, methamphetamine, sibutramine hydrochloride, nafarelin, leuprolide acetate, insulin, growth hormone and analogues thereof, doxazosin, tamsulosin, terazosin, finasteride, alprostadil, sildenafil citrate, bromocriptine, cabergoline, selegiline, melatonin, glimepiride, rosiglitazone, glyburide, glipizide and combinations thereof.

19. The composition according to claim 1, wherein the at least one medicament is present as a single enantiomer.

20. (Currently Amended) The composition according to claim 5 ~~6~~, wherein the at least one permeation enhancer is selected from the group consisting of lipophilic solvents, surfactants, oleic acid, octyl dimethyl benzoic acid, menthol, mixed esters of capric and caprylic acid, polyhydric alcohols, dimethyl sulfoxide, dimethyl formamide, isopropyl myristate, Tween, sodium lauryl sulfate, propylene glycol, transcutol and combinations thereof.

21. (Canceled)

22. (Currently Amended) The composition according to claim 1, wherein the at least one vehicle comprises water, ~~or~~ at least one non-aqueous solvent, or at least one propellant.

23. The composition according to claim 22, wherein the at least one non-aqueous solvent is selected from the group consisting of acetone, isopropyl alcohol, methylene chloride, methyl ethyl ketone, absolute alcohol, ethyl acetate trichloromonofluoroethane (P11) and methylene dimethyl ether.

24. (Canceled)

25. (Currently Amended) The composition according to claim 24 22, wherein the at least one propellant comprises from about 10% to about 90% of the composition.

26. (Currently Amended) The composition according to claim 24 22, wherein the at least one propellant is selected from the group consisting of a hydrocarbon, a hydrofluorocarbon, hydrochlorofluorocarbon, ~~and~~ a compressed gas propane, butane, isobutane, dimethylether, dichlorodifluoromethane (P12), trichloromonofluoromethane (P11), dichlorofluoroethane, monochlorodifluoromethane (P22), dichlorotetrafluoroethane (P114), difluoroethane (P152A), tetrafluoroethane (P134A), heptafluoropropane (P227B), nitrogen and carbon dioxide.

27. (Canceled)

28. The composition according to claim 1, wherein the at least one vehicle comprises from about 1% to about 20% (w/w) of at least one humectant.

29. (Currently Amended) The composition according to claim 28, wherein the at least one humectant is selected from the group consisting of polyhydric alcohols ~~and~~ polyvinyl pyrrolidone, propylene glycol, butylene glycol, a polyethylene glycol, glycerol and sorbitol.

30. (Canceled)

31. The composition according to claim 1, wherein the at least one film-former is selected from the group consisting of acrylic polymers or copolymers, polyvinyl acetate, cellulose acetate, polyvinyl alcohol, povidone, copolypovidone povidone vinyl acetate, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, methyl cellulose and ethyl cellulose.

32. The composition according to claim 31, wherein the acrylic polymer or copolymer is selected from the group consisting of non-ionic copolymers of methyl methacrylate and butyl methacrylate, copolymers of dimethylamine ethyl methacrylate and a neutral methacrylic acid ester, ammonio methacrylate copolymer type B, ammonio methacrylate copolymer type A, methacrylic acid copolymer type A and methacrylic acid copolymer type B.

33. (Currently Amended) The composition according claim ~~7~~ 8, wherein the at least one solubilizer is selected from the group consisting of copolymers of dimethylamine ethyl methacrylate and a neutral methacrylic acid ester, a surfactant, a polyhydric alcohol, vitamin E, vitamin E TPGS (tocopheryl polyethylene 1000 succinate), labrasol, propylene carbonate, sodium lauryl sulphate, Tweens, spans, propylene glycol polyethylene glycol and combinations thereof.

34. (Canceled)

35. (Currently Amended) The composition according to claim ~~9~~ 10, wherein the at least one plasticizer is selected from the group consisting of triethyl citrate, dimethyl isosorbide, acetyltributyl citrate, castor oil, propylene glycol, polyethylene glycol, and combinations thereof.

36. The composition according to claim 11, wherein the at least one water soluble additive is selected from the group consisting of propylene glycol, sodium lauryl sulfate, one or

more polaxomers, polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, cetomacrogol, polyethylene glycol, diethylene glycol, monoethyl ether EP (transcutol), and combinations thereof.

37. (Currently Amended) A ~~The composition for topical application~~ according to claim 1, comprising:

from about 0.0001% to about 30% of at least one medicament for topical or systemic availability,

at least one film-former,

at least one solubilizer,

at least one permeation enhancer,

at least one plasticizer, and

at least one vehicle

said composition forming a stable, breathable film upon application to a surface.

38. The composition according to claim 37, wherein the at least one medicament comprises from about 0.0001% to about 10% of the composition.

39. The composition according to claim 37, wherein the at least one medicament comprises from about 0.0001% to about 5% of the composition.

40. The composition according to claim 37, wherein the at least one film former comprises from about 0.0001% to about 10% of the composition, the at least one solubilizer comprises from about 0.0001% to about 10% of the composition, the at least one permeation

enhancer comprises from about 0.0001% to about 8% of the composition, and the at least one plasticizer comprises from about 0.0001% to about 10% of the composition.

41-43. (Canceled)

44. The composition according to claim 37, further comprising from about 0.0001% to about 7% of at least one water soluble additive.

45. The composition according to claim 37, wherein the film-former is a non-ionic copolymer of methyl methacrylate and butyl methacrylate and the solubilizer is a copolymer of dimethylamine ethyl methacrylate and a neutral methacrylic acid ester.

46. (Currently Amended) A stable, breathable film formed on the skin by topically applying a composition to an intended application site, said composition comprising

from about 0.001% up to about 30% of at least one medicament for topical or systemic availability,

at least one film-former; and

at least one vehicle; and at least one component selected from the group

at least one permeation enhancer;

at least one solubilizer;

at least one plasticizer; and

at least one water soluble additive.



47. The film according to claim 46, wherein the composition comprises up to about 10% of the at least one medicament.

48. The film according to claim 46, wherein the composition comprises up to about 5% of the at least one medicament.

49-51. (Canceled)

52. The film according to claim 46, wherein the film is formed over a fixed surface area.

53. The film according to claim 52, wherein the fixed surface area is less than about 50 cm<sup>2</sup>.

54. The film according to claim 52, wherein the fixed surface area is from about 10 cm<sup>2</sup> to about 25 cm<sup>2</sup>.

55. The film according to claim 46, wherein the at least one medicament is locally or transdermally available.

56. (Currently Amended) A stable, breathable film formed on the skin by topically applying a composition according to claim 37 ~~to an intended application site, said composition comprising~~

~~—— up to about 30% of at least one medicament for topical or systemic availability,~~

~~—— up to about 10% of at least one film former,~~

~~up to about 10% of at least one solubilizer,~~

~~up to about 8% of at least one permeation enhancer,~~

~~up to about 10% of at least one plasticizer, and~~  
~~at least one vehicle.~~

57. (Currently Amended) A method of using at least one medicament, comprising the steps of:

providing a composition for topical application, and

dispensing a metered dose of said composition onto an intended application site on the skin;

wherein the composition comprises ~~up~~ from about 0.0001% to about 30% of at least one medicament for systemic or topical availability,

at least one film former, ~~and~~

at least one vehicle; and at least one component selected from the group

at least one permeation enhancer;

at least one solubilizer;

at least one plasticizer; and

at least one water soluble additive.

58. The method according to claim 57, wherein the composition comprises up to about 10% of the at least one medicament.

59. The method according to claim 57, wherein the composition comprises up to about 5% of the at least one medicament.

60. (Currently Amended) The method according to claim 57, wherein the at least one film former comprises ~~up~~ from about 0.0001% to about 10% of the composition.

61-66. (Canceled)

67. The method according to claim 57, wherein the metered dose is dispensed over a fixed surface area.

68. The method according to claim 67, wherein the fixed surface area is not more than about 50 cm<sup>2</sup>.

69. The method according to claim 68, wherein the fixed surface area is from about 10 cm<sup>2</sup> to about 25 cm<sup>2</sup>.

70. The method according to claim 57, wherein said dispensing comprises spraying.

71. The method according to claim 57, wherein the composition forms a stable, breathable film after dispensing on the application site.

72. The method of claim 70, wherein said dispensing is conducted by an apparatus selected from the group consisting of a pump dispenser and an aerosol dispenser.

73. (Canceled)